UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,866	10/21/2003	Benjamin Oshlack	200.1133CON	3333

7590 11/25/2008

DAVIDSON, DAVIDSON & KAPPEL, LLC
14th Floor
485 Seventh Avenue
New York, NY 10018

EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,866	OSHLACK ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59 and 61-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-59, 61 and 64* is/are rejected.

7)☒ Claim(s) *62 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/08/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114, the Amendment and Applicant's Arguments/Remarks, all filed 09/08/08 is acknowledged. The Information Disclosure Statement (IDS) filed 09/08/08 is also acknowledged.

Claims 1-59 and 61-64 are pending in this action. Claims 1-18, 24, 29-41 and 54 have been amended. New claims 62-64 have been added. Claim 60 has previously been cancelled. Claims 62-63 are objected to. Claims 1-59 and 61 and 64 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 September 2008 has been entered.

* * * * *

Claim Objections

Claims 62-63 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. The claims recite "…oral dosage form of any of claims 1, 2, 3, 4, 5…". The claims should instead recite "any *one* of" rather than "any of". See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-59, 61 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo (WO 99/32120).

Palermo (WO '120) teaches an oral dosage form of an opioid analgesic, comprising an analgesically effective amount of an opioid agonist together with an opioid antagonist, the amount of opioid antagonist including being sufficient to counteract opioid effects if extracted together with the opioid agonist (see p. 6, lines 1-18). Palermo also teach a method of treating pain in human patients which minimizes the likelihood or oral abuse of opioid analgesics, comprising administering an oral dosage form having the combinations of opioid agonist/opioid antagonist (p. 8, lines 10-13).

In certain preferred embodiments, the opioid agonist is hydrocodone, hydromorphone, oxycodone, morphine or pharmaceutically acceptable salts thereof (p. 7, lines 5-6). Suitable opioid antagonists disclosed include naltrexone, naloxone, nalmephene, cyclazocine and levallorphan. A most preferred antagonist is naltrexone (p. 11, lines 14-19); (p. 13, lines 14-31). In certain preferred embodiments of the method, the opioid agonist and the opioid antagonist are combined in a ratio of opioid antagonist to opioid agonist which is analgesically effective when the combination is administered orally, but which is aversive in a physically dependent subject (p. 7, lines 7-15). In embodiments where the opioid is hydrocodone and the antagonist is naltrexone, the ratio of naltrexone to hydrocodone is preferably from about 0.03-0.27:1 by weight (p. 7, lines 15-26).

Palermo teaches that the dosage forms of the invention may be liquids, tablets, multiparticulates, dispersible powders or granules, hard or soft capsules, lozenges, aqueous or oily suspensions, emulsions, syrups, elixirs, microparticles, buccal tablets, etc. (p. 7, lines 27-31); (p. 8, line 29 – p. 9, line 1). In certain preferred embodiments, the oral dosage forms are sustained release formulations. This may be accomplished via the incorporation of a sustained release carrier into a matrix containing the opioid agonist and opioid antagonist; or via a sustained release coating of a matrix containing the opioid agonist and opioid antagonist, where the sustained release coating contains at least a portion of the sustained release carrier included in the dosage form (p. 8, lines 1-9); (p. 20, lines 16-21).

With regards to ratios, Palermo teaches that the combinations of opioid antagonists/opioid agonists which are orally administered in ratios which are equivalent to the ratio of e.g., naltrexone to hydrocodone set forth are considered to be within the scope of the

invention. For example, in some embodiments, naloxone is utilized as the opioid antagonist, the amount of naloxone included in the dosage form being large enough to provide an equiantagonistic effect as if naltrexone were included in the combination (p. 19-31). This demonstrates bioequivalency of the dosage forms.

Palermo teaches that the dosage forms may be coated with one or more materials suitable for the regulation of release or the protection of the formulation. The coatings are provided to permit either pH-dependent or pH-independent release (p.21, lines 18-29).

In preferred embodiments, the substrate (e.g., tablet core bead, matrix particle) containing the opioid analgesic is coated with a hydrophobic material selected from (i) an alkylcellulose; (ii) an acrylic polymer or (iii) mixtures thereof (p. 22, lines 6-14). For instance, the hydrophobic material can be used to coat inert pharmaceutical beads such as non-pareil beads (p. 25, lines 21-26). Spheroids or beads coated with a therapeutically active agent are prepared, e.g., by dissolving the therapeutically active agent in water and then spraying the solution onto a substrate, for example, non-pareil beads. The resultant coated substrate (i.e., beads) may then be optionally overcoated with a barrier agent to separate the therapeutically active agent from the hydrophobic controlled release coating. The beads may then be overcoated with an aqueous dispersion of the hydrophobic material (p. 26, lines 5-17). A combination of two or more hydrophobic materials can be used (p. 30, lines 8-12). This teaching meets Applicant's requirement of the sequestering material comprising, for example, a cellulose polymer or an acrylic polymer, as in instant claims 24-26.

Suitable and preferred alkylcellulose polymers taught include ethylcellulose (p. 22, lines 19-25). Acrylic polymers are also disclosed and include acrylic acid and methacrylic acid

copolymers, methyl methacrylate copolymers, ethoxyethyl methacrylates, cyanoethyl methacrylate, poly(acrylic acid), poly(methacrylic acid) and the like (p. 23, line 10 – p. 24, line 22); (p. 29, lines 7-18). Plasticizers can also be included in the composition (p. 24, line 24 – p. 25, line 20). A process for preparing coated beads is disclosed at p. 25, line 21 – p. 28, line 8. Matrix bead formulations are disclosed at page 28. Hydrophilic and/or hydrophobic materials, such as gums, cellulose ethers, acrylic resins, protein derived materials and any pharmaceutically acceptable hydrophobic material or hydrophilic material, which is capable of imparting, controlled release of the active agent and which melts (or softens to the extent necessary to be extruded) may be used in this invention (p. 28, lines 19-30).

With regards to amounts of hydrophobic material claimed, the Examiner notes that suitable or effective amounts can be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, Palermo teaches that their controlled release profile can be altered, for example, by varying the amount of overcoating with the hydrophobic material (p. 25, lines 27-30).

Regarding the claim limitation of "a sequestering material separating the opioid antagonist from the opioid agonist" as recited, for example, in instant claims 1-7 (and additional claims), it is noted that Palermo does teach the use of an overcoating with a barrier agent, for

instance, to separate the therapeutically active agent from the hydrophobic controlled release coating. The reference further teaches that their beads may then be overcoated with an aqueous dispersion of the hydrophobic material (p. 26, lines 5-17). While Palermo does not indicate that their hydrophobic material/coating (i.e., sequestering material) is provided in a way so as to separate the antagonist from the opioid agonist, it is the position of the Examiner that the prior art does not have to teach this property (separation of agonist from antagonist), but merely that the prior art suggest using the material (hydrophobic material) for any reason. In this instance, since the art does clearly suggest use of the same hydrophobic coating materials (i.e., Applicant's sequestering material) used in the same field of endeavor as the Applicant, burden would be shifted to Applicant to show that the hydrophobic coating materials disclosed by the prior art would not be suitable for their intended function.

With respect to claims pertaining to the effects produced by the opioid antagonist, such as when the dosage is intact or alternatively, tampered with, Palermo sufficiently meets these limitations. Palermo teaches that their dosage forms resist abuse potential and can provide an aversive experience when a large amount of the combination product, e.g., about 2-3 times the usual prescribed dose, is taken by or administered to a physically dependent subject. See for instance, p. 13, lines 4-9. Furthermore, the use of opioid antagonists (i.e., naltrexone) are known to prevent euphorigenic effects of the opioid agonists and also provide a blocking action (p. 12, lines 1-15).

Pertaining to instant claim 64 which presents particular release rates of the antagonist, when the antagonist is intact, Palermo teaches suitable weight ratios for the opioid agonist:antagonist components but does not explicitly teach Applicant's release rates. However,

it is the position of the Examiner that the determination of effective or suitable release profiles is within the level of one of ordinary skill in the art through routine experimentation to obtain optimal results, since these are variable parameters attainable within the art.

With regards to the recitation of an opioid antagonist that is "sequestered", the term "sequestered", even as defined by Applicant's specification, merely requires that the formulation at some point in time be non-releasable (see specification, page 5, lines 23-31). The formulations containing opioid antagonists as disclosed by Palermo would function in the same manner as instantly desired, such as in blocking or reversing the effects of the opioid agonists to avoid or resist misuse and abuse. Hence, no distinction has been observed that would result in a *patentable* distinction based on the instant antagonist versus those (antagonists) disclosed by the art.

The Palermo reference explicitly recognizes and teaches oral dosage forms comprising opioid agonists in combination with opioid antagonists, whereby the dosage forms are effective for the substantial reduction of pain.

Hence, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

* * * * *

Claims 1-59, 61 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaiko *et al.* (hereinafter "Kaiko") (U.S. Pat. No. 6,277,384).

Kaiko ('384) teaches oral dosage forms comprising a combination of an orally analgesically effective amount of an opioid agonist and an orally active opioid antagonist, the

opioid antagonist being included in a ratio to the opioid agonist to provide a combination product which is analgesically effective when the combination is administered orally, but which is aversive in a physically dependent subject (see Abstract); (col. 5, lines 1-18). Kaiko also teaches a method of treating pain comprising the opioid agonist (analgesic) which reducing the abuse potential of the dosage form (column 4, lines 46-67). The method for treatment comprises orally administering an orally analgesically effective amount of an opioid agonist together with an opioid antagonist in a ratio which maintains analgesic efficacy by the opioid analgesic but which may decrease analgesia somewhat by direct measurement in patients or by the use of one or more surrogate measures of opioid effect in human subjects (col. 5, lines 58-64).

Suitable opioid agonists taught include hydrocodone (col. 5, lines 33-37). Additional analgesics are taught at column 11, lines 34-65. Suitable antagonists disclosed include for example, naltrexone (col. 5, lines 33-37). Other antagonists disclosed include naloxone, nalmephene, cyclazocine and levallorphan (col. 10, lines 3-29).

The pharmaceutical compositions may be in the form of tablets, multiparticulate formulations, powders, granules, matrix spheroids or coated inert beads and the like (col. 7, lines 18-27). The dosage forms may provide an immediate release of the opioid agonist and opioid antagonist. In certain embodiments, the dosage forms provide a sustained release of the opioid agonist, and provide the part or all of the dose of the opioid antagonist in (i) immediate release form; (ii) sustained release form or (iii) both immediate release and sustained release form. Sustained release may be accomplished, e.g., via a sustained release carrier into a matrix containing the opioid agonist and opioid antagonist or via a sustained release coating of a matrix

containing the opioid agonist and opioid antagonist (col. 7, lines 27-42). In some embodiments, a combination of two opioid analgesics can be included (col. 7, lines 59-60).

In preferred embodiments, the substrate (e.g., tablet core bead, matrix particle) containing the opioid analgesic is coated with a hydrophobic material selected from (i) an alkylcellulose; (ii) an acrylic polymer or (iii) mixtures thereof (col. 17, lines 28-54). For instance, the hydrophobic material can be used to coat inert pharmaceutical beads such as non-pareil beads (col. 19, lines 45-53). Spheroids or beads coated with a therapeutically active agent are prepared, e.g., by dissolving the therapeutically active agent in water and then spraying the solution onto a substrate, for example, non-pareil beads. The resultant coated substrate (i.e., beads) may then be optionally overcoated with a barrier agent to separate the therapeutically active agent from the hydrophobic controlled release coating. The beads may then be overcoated with an aqueous dispersion of the hydrophobic material (col. 20, lines 1-29). A combination of two or more hydrophobic materials can be used (col. 22, lines 56-62). This teaching meets Applicant's requirement of the sequestering material comprising, for example, a cellulose polymer or an acrylic polymer, as in instant claims 24-26.

Suitable and preferred alkylcellulose polymers taught include ethylcellulose (col. 17, lines 46-54). Acrylic polymers are also disclosed and include acrylic acid and methacrylic acid copolymers, methyl methacrylate copolymers, ethoxyethyl methacrylates, cyanoethyl methacrylate, poly(acrylic acid), poly(methacrylic acid) and the like (col. 18, line 9 – col. 19, line 23). Plasticizers can also be included in the composition col. 19, lines 24-41). A process for preparing coated beads is disclosed at column 19, lines 46-67. Hydrophilic and/or hydrophobic materials, such as gums, cellulose ethers, acrylic resins, protein derived materials and any

pharmaceutically acceptable hydrophobic material or hydrophilic material, which is capable of imparting, controlled release of the active agent and which melts (or softens to the extent necessary to be extruded) may be used in this invention (col. 21, lines 50-57).

Kaiko teaches that the abuse potential of opioid analgesics is surprisingly curtailed by their invention. It is possible to combine in a single oral dosage form an opioid analgesic together with a small amount of opioid antagonist to achieve a product which still provides analgesia but which substantially negates the possibility that a physically dependent human subject will continue to abuse the drug by taking more than one tablet at a time, e.g., 2-3 times more than the usually prescribed dose (col. 13, lines 37-61).

With regards to amounts of hydrophobic material claimed, the Examiner notes that suitable or effective amounts can be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, Kaiko teaches that their controlled release profile can be altered, for example, by varying the amount of overcoating with the hydrophobic material (col. 19, lines 54-67).

Regarding the claim limitation of "a sequestering material separating the opioid antagonist from the opioid agonist" as recited, for example, in instant claims 1-7 (and additional claims), it is noted that Kaiko does teach the use of an overcoating with a barrier agent, for

instance, to separate the therapeutically active agent from the hydrophobic controlled release coating. The beads may then be overcoated with an aqueous dispersion of the hydrophobic material (col. 20, lines 1-29). While Kaiko does not indicate that their hydrophobic material/coating (i.e., sequestering material) is provided in a way so as to separate the antagonist from the opioid agonist, it is the position of the Examiner that the prior art does not have to teach this property (separation of agonist from antagonist), but merely that the prior art suggest using the material (hydrophobic material) for any reason. In this instance, since the art does clearly suggest use of the same hydrophobic coating materials (i.e., Applicant's sequestering material) used in the same field of endeavor as the Applicant, burden would be shifted to Applicant to show that the hydrophobic coating materials disclosed by the prior art would not be suitable for their intended function.

With respect to claims pertaining to the effects produced by the opioid antagonist, such as when the dosage is intact or alternatively, tampered with, Kaiko sufficiently meets these limitations. Kaiko teaches that their dosage forms resist abuse potential and can provide an aversive experience when a large amount of the combination product, e.g., about 2-3 times the usual prescribed dose, is taken by or administered to a physically dependent subject. Furthermore, the use of opioid antagonists (i.e., naltrexone) are known to prevent euphorigenic effects of the opioid agonists and also provide a blocking action.

Pertaining to instant claim 64 which presents particular release rates of the antagonist, when the antagonist is intact, Kaiko teaches suitable weight ratios for the opioid agonist:antagonist components but does not explicitly teach Applicant's release rates. However, it is the position of the Examiner that the determination of effective or suitable release profiles is

within the level of one of ordinary skill in the art through routine experimentation to obtain optimal results, since these are variable parameters attainable within the art.

With regards to the recitation of an opioid antagonist that is "sequestered", the term "sequestered", even as defined by Applicant's specification, merely requires that the formulation at some point in time be non-releasable (see specification, page 5, lines 23-31). The formulations containing opioid antagonists as disclosed by Kaiko would function in the same manner as instantly desired, such as in blocking or reversing the effects of the opioid agonists to avoid or resist misuse and abuse. Hence, no distinction has been observed that would result in a *patentable* distinction based on the instant antagonist versus those (antagonists) disclosed by the art.

The Kaiko reference explicitly recognizes and teaches oral dosage forms comprising opioid agonists in combination with opioid antagonists, whereby the dosage forms are effective for the substantial reduction of pain.

Hence, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

* * * * *

Response to Arguments

Applicant's arguments filed 09/08/08 have been fully considered but were not found to be persuasive.

- **Rejection under 35 U.S.C. §103(a) over Palermo (WO 99/32120):**

Applicant argued, "The Palermo Publication describes dosage forms in which an opioid antagonist and an opioid agonist are combined in such a way that at least a two-step extraction process would be required to separate the opioid antagonist from the opioid agonist."

Applicant's arguments have been fully considered, but were not deemed persuasive. The arguments for the necessity of using a two-step extraction process for separation are not pertinent to the obviousness of the claimed formulation.

Applicant argued, "Palermo does not teach or suggest an opioid agonist separated from the opioid antagonist as recited in the amended independent claims."

This argument was not persuasive. While Palermo does not indicate that their hydrophobic material/coating (i.e., sequestering material) is provided in a way so as to separate the antagonist from the opioid agonist, it is the position of the Examiner that the prior art does not have to teach this property (separation of agonist from antagonist), but merely that the prior art suggest using the material (hydrophobic material) for any reason. In this instance, since the art does clearly suggest use of the same hydrophobic coating materials (i.e., Applicant's sequestering material) used in the same field of endeavor as the Applicant, burden would be shifted to Applicant to show that the hydrophobic coating materials disclosed by the prior art would not be suitable for their intended function. Furthermore, no unexpected results have been demonstrated by the separation of the agonist from antagonist. The prior art clearly teaches the use of hydrophobic materials to affect release of active ingredient as well as barrier layers as a means of providing separation between components of the composition.

Applicant argued, "Palermo does not teach the degree of sequestration recited as in claims 1-7."

This argument was not persuasive since the degree of sequestration argued by Applicant does not demonstrate that the instant invention would be materially different than the compositions of the art, which teaches use of the same components, in a similar manner to yield similar effects and results and treats the same problems (i.e., pain) as that desired by Applicant. Moreover, the difference would be only a difference in degree and not of kind.

The rejections of record have been maintained.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

November 24, 2008